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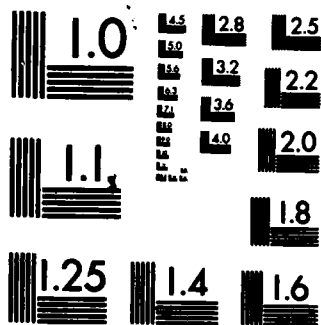
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**UNITED STATES ARMY
ENVIRONMENTAL HYGIENE
AGENCY**

ABERDEEN PROVING GROUND, MD 21010

NONIONIZING RADIATION PROTECTION SPECIAL STUDY NO. 25-42-0340-83
DYNATRON MODEL DT-820 HELIUM-NEON (HeNe) LASER
APRIL 1983

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A Nonionizing Radiation Protection Special Study of the Dynatron Model DT-820 HeNe Laser was performed by this Agency at Walter Reed Army Medical Center. It was determined that the Dynatron Model DT-820 laser was a Class 2 laser system and the laser radiation emitted from the Dynatron did not present a hazard to the skin. ↑		

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

1LT Armstrong/Jr/AUTOVON
584-3932

REPLY TO
ATTENTION OF

HSNB-RL/WP

7 JUN 1983

SUBJECT: Nonionizing Radiation Protection Special Study No. 25-42-0340-83,
Dynatron Model DT-820 HeNe Laser, April 1983

Commander
US Army Health Services Command
ATTN: HSPA-P
Fort Sam Houston, TX 78234

EXECUTIVE SUMMARY

The purpose, essential findings, and major recommendations of the inclosed report follow:

a. Purpose. The purpose of this report is to determine if the laser radiation emitted by the Dynatron Model DT-820 Helium-Neon laser exceeds current exposure limits and to make recommendations to eliminate exposure of personnel to potentially hazardous laser radiation.

b. Essential Findings. The Dynatron Model DT-820 laser is a Class 2 laser system and the laser radiation emitted from the Dynatron does not present a hazard to the skin. However, personnel should not attempt to stare directly into the beam.

c. Major Recommendations. Do not point the Dynatron Model DT-820 laser into the eyes of patients.

FOR THE COMMANDER:

1 Incl
as (3 cy)

Joseph T. Whitlaw, Jr
JOSEPH T. WHITLAW, JR
Colonel, MSC
Director, Radiation and
Environmental Sciences

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

REPLY TO
ATTENTION OF

HSNB-RL/WP

NONIONIZING RADIATION PROTECTION SPECIAL STUDY NO. 25-42-0340-83
DYNATRON MODEL DT-820 HELIUM-NEON (HeNe) LASER
APRIL 1983

1. **AUTHORITY.** Letter, HSHL-HP, Walter Reed Army Medical Center, 26 October 1982, subject: Evaluation of Laser Acupuncture Investigational Medical Device, and indorsement thereto.
2. **REFERENCES.** See Appendix A for a listing of references.
3. **PURPOSE.** To evaluate possible optical radiation hazards associated with the Dynatron Model DT-820 Helium-Neon (HeNe) laser and to make recommendations necessary to eliminate exposure of personnel to potentially hazardous optical radiation from this device.
4. **GENERAL.**
 - a. **Background.** The Dynatron Model DT-820 HeNe Laser was obtained by the Pain Control Clinic, Walter Reed Army Medical Center (WRAMC), from Dynatronics Research Corporation, Salt Lake City, Utah 84104, for consideration for possible use as a laser "biostimulator." An extensive literature on "laser biostimulation" has accumulated in recent years (Appendix B). Many claims have been made in these reports to the effect that low power coherent light has certain properties to stimulate wound healing, pain relief, etc., at levels below thermal heating. In the United States, most of these reports have been met with great skepticism. However, there has been a need to conduct an unbiased study of these effects. The WRAMC Pain Control Clinic planned to use this device to test by objective means these claims found in the literature.
 - b. **Description.** The Dynatron Model DT-820 is a HeNe laser operating at 632.8 nm. The laser radiation is delivered through a flexible fiber optic light guide to a hand-held stylus. The system may be operated in the pulsed mode from 2.5 Hz to 200 Hz. In the pulsed mode, the beam is mechanically chopped with 50 percent duty cycle. The system is portable and is operated from 120 V AC. The Figure shows an illustration of the Dynatron laser.
 - c. **Inventory.** One Dynatron Model DT-820 laser [Serial Number (SN) EXP .2] was on hand at the Pain Control Clinic, WRAMC, Room 6344, Ward 63.
 - d. **Instrumentation.**
 - (1) United Detector Technology Inc. (UDT) Model 40X Optometer (SN 45101).
 - (2) Tektronix Model 214 Storage Oscilloscope (SN B111999).
 - e. **Radiometric Terms and Units.** Radiometric terms and units are listed in Appendix C.

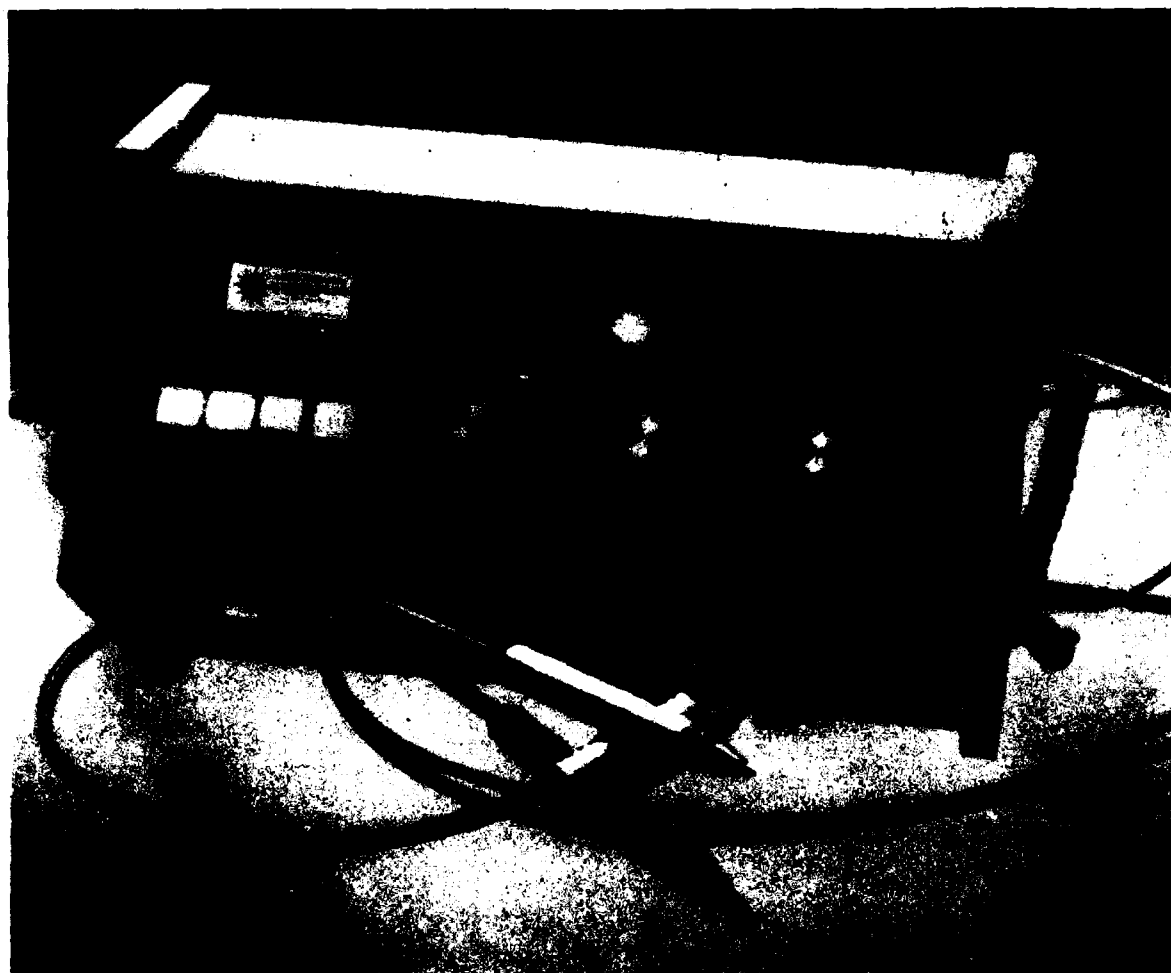


Figure 1. The Dynatron Model DT-820 HeNe Laser.

5. FINDINGS.

a. Radiometric Measurements. Radiometric measurements were made on the Dynatron Model DT-820, SN EXP .2, at the Pain Control Clinic, WRAMC, on 31 March 1983. The results of these measurements are as follows:

(1) Continuous Wave Mode.

Radiant Power: 0.89 mW
Beam Divergence: 27° at 1/e points

(2) Pulsed Mode. The Table provides values of the measured frequency and the average power for various frequency settings. An indicated frequency of 29 Hz gave the maximum average power of 0.67 mW.

TABLE. LASER OUTPUT MEASUREMENTS

INDICATED FREQUENCY Hz	MEASURED FREQUENCY Hz	AVERAGE POWER mW
<u>Low Mode</u>		
2.5	2.9	0.41
10	26.3	0.39
20	28.6	0.42
25	34.5	0.52
<u>High Mode</u>		
25	28.6	0.48
29	----	0.67
30	40	0.54
60	76.9	0.40
80	125	0.40
140	166.7	0.40
160	188.7	0.40
200	200	0.40

b. Manufacturer's Measured Parameters.

(1) Continuous Wave Mode.

Radiant Power: 0.95 mW
Beam Divergence: 30°

(2) Pulsed Mode. Average Power at 80 Hz: 0.45 mW

c. Federal Performance Standard. The appropriate warnings were permanently attached to the device housing and other system safety features were present as prescribed in 21 CFR 1040.

d. Investigational Device Exemption (IDE). At the time of the study the WRMC Pain Control Clinic was preparing an IDE for submission to their Human Use Committee.

6. DISCUSSION.

a. Laser Hazard Classification. The maximum radiant power of the Dynatron Model DT-820 HeNe laser is 0.89 mW. This is greater than the Class 1 emission limit for visible lasers of 0.4 uW and less than the Class 2 emission limit for visible lasers of 1 mW. Therefore, this laser is classified from a hazard standpoint as a Class 2, low power laser. The potential hazard from this laser is limited to the eye, and it does not pose a skin or fire hazard. A retinal injury could result if an individual were to stare within the direct laser beam or a specularly reflected beam. However, an individual's natural aversion response (blink reflex) to the extremely bright light from this laser would limit the exposure to a level below current protection standards; therefore, this laser does not pose a significant hazard to the eye.

b. Exposure Limit. The exposure limit for staring directly into the beam of the Dynatron Model DT-820 laser was calculated to be 10 s at a distance of 2 cm and 8 hr at a distance of 70 cm.

7. CONCLUSION. The Dynatron Model DT-820 laser does not present a hazard during normal use. However, personnel should not attempt to stare directly into the beam.

8. RECOMMENDATION. Do not point the Dynatron Model DT-820 laser into the eyes of patients [para 5-38b(5), AR 40-5].

David H. Sliny
DAVID H. SLINEY
Chief, Laser Branch
Laser Microwave Division

Brett C. Armstrong
BRETT C. ARMSTRONG
1LT, MSC
Nuclear Medical Science Officer
Laser Microwave Division

APPROVED:

Charles E. Day, III
CHARLES E. DAY, III
MAJ, MSC
Chief, Laser Microwave Division

APPENDIX A

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4. Title 21, Code of Federal Regulations (CFR), 1982 rev, Part 812, Investigational Device Exemptions.
5. Title 21, CFR, 1982 rev, Part 1040, Performance Standards for Light-Emitting Products.
6. Letter, HSHL-SAO, Walter Reed Army Medical Center, 18 April 1983, subject: Effects of Biostimulation with Laser for Relief of Chronic Pain.

APPENDIX B

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APPENDIX C

USEFUL CIE RADIOMETRIC AND PHOTOMETRIC TERMS AND UNITS^{1,2}

RADIOMETRIC				PHOTOMETRIC			
Term	Symbol	Defining Equation	SI Unit and Abbreviation	Term	Symbol	Defining Equation	SI Units and Abbreviation
Radiant Energy	Q_e		Joule (J)	Quantity of Light	Q_v	$Q_v = \int \phi_v dt$	lumen-second (lm-s)
Radiant Energy Density	U_e	$U_e = \frac{dQ_e}{dV}$	Joule per cubic meter (J-m ⁻³)	Luminous Energy Density	U_v	$U_v = \frac{dQ_v}{dV}$	candela per square meter (cd-m ⁻²)
Radiant Power (Radiant Flux)	$Q_e \cdot P$	$Q_e \cdot P = \frac{dQ_e}{dt}$	Watt (W)	Luminous Flux	Φ_v	$\Phi_v = 400 \int \frac{dQ_e}{d\lambda} V(\lambda) d\lambda$	lumen (lm)
Radiant Exitance	M_e	$M_e = \frac{dQ_e}{dA} = \int L_e \cos \theta d\Omega$	Watt per square meter (W-m ⁻²)	Luminous Exitance	M_v	$M_v = \frac{dQ_v}{dA} = \int L_v \cos \theta d\Omega$	lumen per square meter (lm-m ⁻²)
Irradiance or Radiant Flux Density (Does Not Have a Photobiology)	E_e	$E_e = \frac{dQ_e}{dA}$	Watt per square meter (W-m ⁻²)	Illuminance (Luminous Flux Density)	E_v	$E_v = \frac{dQ_v}{dA}$	lumen per square meter (lm-m ⁻²) lux (lx)
Radiant Intensity	I_e	$I_e = \frac{dQ_e}{d\Omega}$	Watt per steradian (W-sr ⁻¹)	Luminous Intensity (Candela Power)	I_v	$I_v = \frac{dQ_v}{d\Omega}$	lumen per steradian (lm-sr) or candela (cd)
Radiance	L_e	$L_e = \frac{d^2 Q_e}{dA d\Omega \cos \theta}$	Watt per steradian and per square meter (W-sr ⁻¹ -m ⁻²)	Luminance	L_v	$L_v = \frac{d^2 Q_v}{dA d\Omega \cos \theta}$	candela per square meter (cd-m ⁻²)
Radiant Exposure (Does Not Have a Photobiology)	H_e	$H_e = \frac{dQ_e}{dA}$	Joule per square meter (J-m ⁻²)	Light Exposure	H_v	$H_v = \frac{dQ_v}{dA} = \int L_v dt$	lux-second (lx-s)
				Luminous Efficacy (of radiation)	η	$\eta = \frac{\Phi_v}{Q_e}$	lumen per watt (lm-W ⁻¹)
				Luminous Efficacy (of a broad band radiation)	$V(\lambda)$	$V(\lambda) = \frac{L_v}{L_e} = \frac{\eta}{\eta_0}$	unitless
Radiant Efficiency ³ (of a source)	η_e	$\eta_e = \frac{P}{P_i}$	unitless	Luminous Efficacy ³ (of a source)	η_v	$\eta_v = \frac{\Phi_v}{P_i}$	lumen per watt (lm-W ⁻¹)
Optical Density ⁴	D_o	$D_o = -\log_{10} T_o$	unitless	Optical Density ⁴	D_v	$D_v = -\log_{10} T_v$	unitless

1. The units may be altered to refer to narrow spectral bands in which case the term is preceded by the word "spectral", and the unit is then per wavelength interval and the symbol has a subscript λ . For example, spectral irradiance $E_{e\lambda}$ has units of W-m⁻²-nm⁻¹ or more often, W-cm⁻²-nm⁻¹.

2. While the meter is the preferred unit of length, the centimeter is still the most commonly used unit of length for many of the above terms and the m or cm are most commonly used to express wavelength.

3. P_i is electrical input power in watts. 4. τ is the transmission. 5. At the source $I_e = \frac{dQ_e}{dA \cos \theta}$ and at a receptor $I_e = \frac{dQ_e}{dA}$.

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